



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

Amd Group LLC
Scott Edwards
Director, Quality Assurance And Regulatory Affairs
7405 Westfield Blvd.
Indianapolis, Indiana 46240

November 25, 2015

Re: K152939

Trade/Device Name: Picasso Plus, Picasso Lite Plus

Regulation Number: 21 CFR 878.4810

Regulation Name: Laser Surgical Instrument For Use In General And Plastic Surgery And
In Dermatology

Regulatory Class: Class II

Product Code: GEX

Dated: October 2, 2015

Received: October 5, 2015

Dear Scott Edwards:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the [Federal Register](#).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-

related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Joshua C. Nipper -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K152939

Device Name

Picasso Plus and Picasso Lite Plus

Indications for Use (Describe)

The Picasso Plus / Picasso Lite Plus is generally indicated for incision, excision, vaporization, ablation and coagulation of oral soft tissues including the following: Gingival troughing for crown impression; Gingivectomy; Gingivoplasty; Gingival incision and excision; Hemostasis and coagulation; Excisional and incisional biopsies; Exposure of unerupted teeth; Fibroma removal; Frenectomy and frenotomy; Implant recovery; Incision and drainage of abscess; Leukoplakia; Operculectomy; Oral papillectomies; Pulpotomy; Pulpotomy as an adjunct to root canal therapy; Reduction of gingival hypertrophy; Soft tissue crown lengthening; Treatment of canker sores, herpetic and aphthous ulcers of the oral mucosa; and Vestibuloplasty.

Laser Periodontal Procedures, including: Sulcular debridement (curettage, removal of diseased, infected, inflamed and necrosed soft tissue in the periodontal pocket to improve clinical indices including: gingival index, gingival bleeding index, probe depth, attachment loss and tooth mobility); Removal of highly inflamed edematous tissue affected by bacteria penetration of the pocket lining and junctional epithelium; and Picasso assisted new attachment procedure (cementum-mediated periodontal ligament new-attachment to the root surface in the absence of long junctional epithelium).

Teeth Whitening Indications (Picasso Plus Only): Laser assisted whitening of teeth and Light activation for whitening materials for teeth whitening.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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AMD GROUP LLC | Premarket Notification Special 510(k) Submission Under 21 CFR § 807.87 for Picasso Plus and Picasso Lite Plus

510(k) Summary

As required by the Safe Medical Devices Act (SMDA) of 1990 and in accordance with 21 CFR § 807.92, 510(k) summary is provided.

DATE: November 23, 2015

I. SUBMITTER

AMD GROUP LLC *dba* AMD LASERS
7405 Westfield Blvd
Indianapolis, IN 46240
USA

Phone: 866-999-2635
Fax: 678-868-4108

Contact Person: Scott A. Edwards
Date Prepared: November 9, 2015

II. OFFICIAL CORRESPONDENCE/CONTACT PERSON

Scott A. Edwards
Director of QA/RA
AMD GROUP LLC
Phone: 866-999-2635 x900
e-mail: scott@amdlasers.com

III. 510(K) PREPARER

Scott A. Edwards
Director of QA/RA
AMD GROUP LLC
Phone: 866-999-2635 x900
e-mail: scott@amdlasers.com

IV. DEVICE

Brand Name of Device: Picasso Plus and Picasso Lite Plus
Common or Usual Name: Laser Instrument, Surgical, Powered
Classification Name: Laser surgical instrument for use in general and plastic surgery and in dermatology (21CFR 878.4810)
Regulatory Class: II
Product Code: GEX
510(k) Number: K152939

**AMD GROUP LLC | Premarket Notification Special 510(k) Submission Under 21
CFR § 807.87 for Picasso Plus and Picasso Lite Plus**

V. PREDICATE DEVICE

Device Trade Name: Picasso and Picasso Lite
Device Company: AMD LASERS
510(k) Numbers: K083142 and K102359

VI. DEVICE DESCRIPTION

The Picasso line of soft tissue dental lasers is designed for a wide variety of oral soft tissue surgical, non-surgical, and teeth whitening procedures. Picasso Plus and Picasso Lite Plus lasers employ semiconductor diodes as a laser energy source. The energy is delivered to the operating area by means of a delivery system consisting of a flexible fiber connecting the laser source and the handpiece. The laser delivery used may be in the form of strippable fiber or a multi-tip handpiece that is used in conjunction with disposable tips. The device is activated by means of a wireless footswitch.

VII. INDICATIONS FOR USE

The Picasso Plus /Picasso Lite Plus is generally indicated for incision, excision, vaporization, ablation and coagulation of oral soft tissues including the following:

- Gingival troughing for crown impression
- Gingivectomy
- Gingivoplasty
- Gingival incision and excision
- Hemostasis and coagulation
- Excisional and incisional biopsies
- Exposure of unerupted teeth
- Fibroma removal
- Frenectomy and frenotomy
- Implant recovery
- Incision and drainage of abscess
- Leukoplakia
- Operculectomy
- Oral papillectomies
- Pulpotomy
- Pulpotomy as an adjunct to root canal therapy
- Reduction of gingival hypertrophy
- Soft tissue crown lengthening
- Treatment of canker sores, herpetic and aphthous ulcers of the oral mucosa
- Vestibuloplasty

**AMD GROUP LLC | Premarket Notification Special 510(k) Submission Under 21
CFR § 807.87 for Picasso Plus and Picasso Lite Plus**

Laser Periodontal Procedures, including:

- Sulcular debridement (curettage, removal of diseased, infected, inflamed and necrosed soft tissue in the periodontal pocket to improve clinical indices including: gingival index, gingival bleeding index, probe depth, attachment loss and tooth mobility)
- Removal of highly inflamed edematous tissue affected by bacteria penetration of the pocket lining and junctional epithelium
- Picasso assisted new attachment procedure (cementum-mediated periodontal ligament new-attachment to the root surface in the absence of long junctional epithelium).

Teeth Whitening Indications (Picasso Plus Only):

- Laser assisted whitening of teeth
- Light activation for whitening materials for teeth whitening

VIII. SUBSTANTIAL EQUIVALENCE

K083142: Picasso

K102359: Picasso and Picasso Lite

IX. PERFORMANCE DATA DEMONSTRATING SUBSTANTIAL EQUIVALENCE

The Picasso Plus and Picasso Lite Plus devices have the same intended use and operating principles, with similar design features, and functional and performance characteristics as the previously-cleared devices. The devices are designed to comply with relevant federal and international safety and performance standards. Conformance to these standards, coupled with no changes in the Indications for Use and no change in the fundamental scientific technology demonstrates substantial equivalence to the predicate devices.

**AMD GROUP LLC | Premarket Notification Special 510(k) Submission Under 21
CFR § 807.87 for Picasso Plus and Picasso Lite Plus**

X. SUMMARY OF SIMILARITIES AND DIFFERENCES

The intended use and indications for use of the proposed Picasso Plus and Picasso Lite Plus devices are unchanged from the legally marketed predicate devices Picasso and Picasso Lite. The fundamental scientific technology of the proposed devices is unchanged from the legally marketed predicate device. The design changes implemented in the Picasso Plus and Picasso Lite Plus were aimed at improving functionality and enhancing user experience. The predicate devices and submitted devices share similar design features including identical wavelength, operating controls, and laser delivery method. The devices share similar methods of control systems, safety features, and operation. The devices share similar performance specifications including power output and energy type.

XI. CONCLUSIONS

The Picasso Plus and Picasso Lite Plus lasers are substantially equivalent to the listed predicate devices (Picasso and Picasso Lite lasers) without raising any new issues of safety or effectiveness. The new devices have the same intended use and operating principles, with similar design features, and functional and performance characteristics. The device is designed to comply with relevant federal and international safety and performance standards.